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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/336,091	06/18/1999	JACQUES VAN SNICK	L0461/7063-J	7247

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	18

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/336,091	Van Snick et al.
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2, 5, 7, 9, 14, 16, 18, 21, 23, 29, 33, 37, 43, 50, 57, 61, 68, 72,* 76-83 is/are pending in the application.

4a) Of the above, claim(s) *16, 18, 21, 23, 29, 33, 37, 43, 50, 57, 61, 68, and* 72 is/are withdrawn from consideration.

5) ☒ Claim(s) *77* is/are allowed.

6) ☒ Claim(s) *2, 5, 7, 9, 14, 76, and 78-83* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/15/2002 has been entered.

2. Claims 2,5,7,9,14,76-83 are under consideration. Claims 2,5,7,9,14,76-82 have been amended.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 9,80-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Fikes et al. (WO 95/04542).

Claim 9 recites a composition comprising two peptides that can be physically joined. While the HLA class II binding portion of the peptide consists of a peptide of a maximum of 33 amino acids, said peptide is joined to a MAGE-A1 class I binding peptide of undefined length creating a conjugate that is "open" in length (can be any length). Fikes et al. teach a peptide comprising SEQ. ID. no. 7 (see page 14, last paragraph to page 16 and claim 8, wherein said vector produces the peptide comprising SEQ. ID. no. 7). Said peptide is derived from MAGE A1 (alias MAGE 1). It is an inherent property of the SEQ. ID. no. 7 portion of said peptide that it binds HLA class II HLA DRB1*15. Said MHC class II binding portion of the peptide is the same length as SEQ. 1D. No. 7. Said peptide also contains a MAGE 1 HLA class I binding peptide (eg. it is a polytope polypeptide). Fikes et al. teach compositions of said peptide (see page 17).

Regarding applicants comments, claim 9 comprises two peptides that can be physically joined. While the HLA class 11 binding portion of the peptide consists of a peptide of a maximum of 33 amino acids, said peptide is joined to a MAGE-A1 class 1 binding peptide of undefined

length creating a conjugate that is "open" in length.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 9,14,80-83 rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. (WO 95/04542) in view of Sanderson et al.

Claim 9 recites a composition comprising two peptides that can be physically joined. While the HLA class II binding portion of the peptide consists of a peptide of a maximum of 33 amino acids, said peptide is joined to a MAGE-A1 class I binding peptide of undefined length creating a conjugate that is "open" in length (can be any length). Fikes et al. teach a peptide comprising SEQ. 1D. no. 7 (see page 14, last paragraph to page 16 and claim 8, wherein said vector produces the peptide comprising SEQ. ID. no. 7). Said peptide is derived from MAGE A1 (alias MAGE 1). The SEQ. ID. no. 7 portion of said peptide binds HLA class II HLA DRB1*15. Said MHC class 1l binding portion of the peptide is the same length as SEQ. ID. No. 7. Said peptide also contains a MAGE 1 HLA class I binding peptide (eg. it is a polytope polypeptide). Fikes et al. teach compositions of said peptide (see page 17). Fikes et al. do not teach use of a Ii chain derived endosomal targeting signal in said peptide. Fikes et al. teach MAGE 1 peptide conjugates containing a MAGE 1 class binding peptide and a MAGE 1 class II binding peptide (see page 12, last paragraph). Sanderson et al. teach that addition of a 1i chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class 1l binding/T cell recognition (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. teach MAGE 1 peptide conjugates containing a MAGE 1 class binding peptide and a MAGE 1 class II binding peptide while Sanderson et al. teach that addition of a 1i chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T cell recognition. One of ordinary skill in the art would have been motivate to do the aforementioned because Sanderson et al. teach that addition of a 1i chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T

cell recognition.

Applicants arguments have been addressed in the other prior art rejections.

7. Claims 2,76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. (WO 95/04542).

Fikes et al. teach a peptide that contains all of the amino acids of SEQ. ID. No. 7 except the first and last amino acids (see claim 4, Seq. Id. No. 15). Said peptide is derived from MAGE A1 (alias MAGE 1). Claims 2 and 76 encompass a peptide that has one amino acid deleted from SEQ. ID. No. 7. Thus, the peptide taught by Fikes et al. differs from the invention of claims 2 and 76 by one amino acid. Fikes et al. teach that the amino acid residue Glu can be added at the N-terminus of said peptide (see page 10, last paragraph). This would yield the peptide of claims 2 and 76, wherein said peptide would bind HLA DRB*15 because it is the peptide recited in the claim. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention that differs from the prior art by addition of a single amino acid because Fikes et al. teach a peptide that contains all of the amino acids of SEQ. ID. No. 7 minus one amino acid, except the first amino acid and Fikes et al. teach that the amino acid residue Glu can be added at the N-terminus of said peptide (see page 10, last paragraph). One of ordinary skill in the art would have been motivated to do the aforementioned because Fikes et al. teach that the added residue can be used for conjugating other moieties to the peptide.

Regarding applicants comments and claims 2 and 76, Fikes et al. teach a peptide that contains all of the amino acids of SEQ. ID. No. 7 except the first and last amino acids (see claim 4, Seq. Id. No. 15). Said peptide is derived from MAGE A1 (alias MAGE 1). Claims 2 and 76 encompass a peptide that has one amino acid deleted from SEQ. ID. No. 7. Thus, the peptide taught by Fikes et al. differs from the invention of claims 2 and 76 by one amino acid. Fikes et al. teach that the amino acid residue Glu can be added at the N-terminus of said peptide (see page 10, last paragraph). This would yield the peptide of claims 2 and 76, wherein said peptide would bind HLA DRB*15 because it is the peptide recited in the claim. One of ordinary skill in the art would have been motivated to do the aforementioned because Fikes et al. teach that the added residue can be used for conjugating other moieties to the peptide.

8. Claims 5,78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al.

(WO 95/04542) as applied to claims 2 and 76 above, and further in view of Sanderson et al.

The previous rejection teaches the claimed invention except for use of a Ii chain derived endosomal targeting signal. Fikes et al. teach MAGE 1 peptide conjugates containing a MAGE 1 class binding peptide and a MAGE 1 class II binding peptide (see page 12, last paragraph). Sanderson et al. teach that addition of a Ii chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T cell recognition (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. teach MAGE 1 peptide conjugates containing a MAGE 1 class binding peptide and a MAGE 1 class II binding peptide while Sanderson et al. teach that addition of a Ii chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T cell recognition. One of ordinary skill in the art would have been motivate to do the aforementioned because Sanderson et al. teach that addition of a Ii chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T cell recognition.

Applicants arguments have been addressed in the other prior art rejections.

9. Claims 7,79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. (WO 95/04542) as applied to claims 2 and 76 above, and further in view of Gelder et al. (US Patent 6,043,347).

The previous rejection teaches the claimed invention except for a peptide containing D-amino acids. Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides have increased stability (see column 20). Said peptides would also be non-hydrolyzable because D-amino acid modified peptides have this property (eg. see claim 7 upon which claim 79 depends). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. teach the claimed peptide except for D-amino acid modification, while Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides exhibit increased stability. One of ordinary skill in the art would have been motivate to do the aforementioned because Gelder et al. that teach modified peptides containing D-amino acids have increased stability.

Applicants arguments have been addressed in the other prior art rejections.

10. Claim 77 is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3974. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644